83. A composition according to Claim 20 comprising also a preservative.

84. A composition according to Claim 20 in the form of a composition for administration by topical, oral, parenteral, intranasal, subcutaneous, or intraocular routes.--

REMARKS

Applicants traverse hereby the Examiner's Requirement for Restriction (hereafter "Requirement") and request respectfully reconsideration and withdrawal or modification of the Requirement.

Discussion of the Examiner's Requirement

The Examiner's Action consists of a 26-part requirement for restriction. The basis for the Requirement is that the Examiner considers the inventions of the various groups of claims to be distinct from each other.

It is submitted respectfully that the Examiner's Requirement is deficient on its face because 35 U.S.C. §121 requires that the involved inventions be also independent. Clearly, the inventions which are defined in the various groups of claims are not independent in that there exists a disclosed relationship among the inventions in that they are related as compositions and

methods for use in increasing the level of high density lipoprotein (HDL) cholesterol and apolipoprotein AI in a patient and lowering the level of very low density lipoprotein (VLDL) cholesterol and low density lipoprotein (LDL) cholesterol in a patient.

The Examiner has recognized apparently that the claim groups do not define independent inventions because he has not characterized them as being independent. Moreover, the Examiner has not even attempted in his Action to explain why he considers the claims to be directed to independent inventions. Consequently, the Examiner has issued a Requirement that is deficient on its face because he has not explained why the various claims groups are considered to define independent subject matter. Accordingly, the Requirement should be withdrawn.

It is submitted further that the Examiner's Requirement should be withdrawn because it is believed that a proper search of the subject matter of any one of the groups of claims cannot be done except that a search is conducted for the subject matter of all groups of claims. This is so because the subject matter of the claims is so interrelated.

Furthermore, the Examiner's attention is directed to the

claims of Group IX (Claim 20), which defines a composition comprising LIPG polypeptide, and of Group XVI (Claim 46), which defines a method for lowering VLDL by increasing LIPG activity, and of Group XIX (Claim 52), which defines a method for lowering LDL by increasing LIPG enzymatic activity.

The Examiner has indicated that the subject matter of Claims 46 and 52 is classified in Class 514, Subclass 2 (hereafter "Class 514/2"), which relates to drug and bio-affecting compositions containing a peptide. The Examiner has indicated further that the subject matter of Claim 20 is classified in Class 435, Subclass 198 (hereafter "Class 435/198"), which relates to lipases. It is submitted respectfully that the subject matter of Claim 20 is not properly classified in Class 435/198, but should be classified in Class 514/2 like the subject matter of Claims 46 and 52. Please consider the following.

The classification guidelines in the Manual of Classification provide that Class 435 should only include enzyme-containing compositions when they are "not otherwise provided for." The guidelines go on to state, "[i]n general, [Class 435] will not provide for compositions other than an immobilized or insolubilized enzyme or a test or culture media." In contrast, Class 20 defines a composition comprising an LIPG polypeptide which may or may not be solubilized in solution. The LIPG

polypeptide is not necessarily immobilized or insolubilized and, in addition, it is also not necessarily present in a test or culture media. Accordingly, the subject matter of Claim 20 is not properly classifiable in Class 435.

It is, however, properly classified in Class 514/2. The guidelines in the Manual of Classification for Class 514 are the same as those for Class 424, with the guidelines providing that Class 424 (and hence Class 514) should include

> "[d]rug and bio-affecting compositions which are generally capable of: 1. Preventing, alleviating, treating, or curing abnormal and pathological conditions of the living body by such means as: (a) destroying a parasitic organism; (b) limiting the affect of the disease or abnormality by chemically altering the physiology of the host or parasite..."

The subject matter of independent Claim 20 (and Claims 66 to 84 which depend from Claim 20) is a pharmaceutical composition which increases the level of LIPG polypeptide in a patient and which comprises an LIPG polypeptide. As stated in the present application at page 27, lines 21 to 29, such compositions raise the level of LIPG polypeptide in a patient. This in turn has the effect of lowering the levels of VLDL and LDL cholesterol in the patient. Studies have shown that lowering the level of such cholesterols reduces the risk of atherosclerotic diseases. The composition defined by Claim 20 is, therefore, a "bio-affecting composition" capable of "limiting the affect of the disease or abnormality by chemically altering the physiology of the host."

Accordingly, the subject matter of Claim 20 and its dependent claims should be reclassified in Class 514/2.

There is an additional reason why the Examiner's restriction requirement should be withdrawn with respect to Claim 20 and Claims 46 and 52. Section 803 of the MPEP provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions". Applicants submit respectfully that, since Claim 20 and Claims 46 and 52 involve a LIPG polypeptide, a proper search of the subject matter of the involved claims can be conducted without serious burden.

Applicants make hereby a provisional election of to prosecute Claim 20 (Group IX) and added Claims 66 to 84 which are dependent from Claim 20 and which define a composition comprising LIPG polypeptide.

Discussion of the Amendments

Support for the amendment to Claim 20 is found in the application at page 59, lines 9 to 27, page 60, lines 1 to 29, and page 61, lines 1 to 19.

Support in the application for the added claims is as

follows: Claim 66 - page 16, lines 20 to 24; Claim 67 - page 18, lines 15 to 20; Claim 68 - page 18, lines 21 to 26; Claims 69 to 76 - page 35, lines 23 to 28, page 36, lines 1 to 29, and page 37, lines 1 and 2; Claim 77 - Claim 20 as originally filed; Claim 78 - page 59, lines 10 to 13; and Claims 79 to 84 - page 59, lines 9 to 27, and page 60, lines 1 to 11.

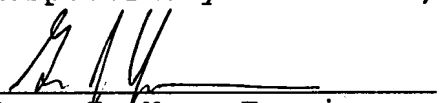
The amendment to the sentence on page 59, line 12, of the descriptive portion of the application makes the disclosure thereof consistent with the disclosure of the sentence on page 59, line 14.

Conclusion

In view of the foregoing amendments and remarks, an early and favorable action is requested respectfully.

Enclosed herewith in duplicate is a Petition for extension of time to respond to the Examiner's Requirement.

Respectfully submitted,



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